

**REMARKS**

Claims 1, 5-14 and 17-20 are pending. Claims 15-16 and 21-23 are canceled without prejudice or disclaimer.

The amendments are supported by the original disclosure and, thus, no new matter has been added. If the Examiner should disagree, however, it is respectfully that the challenged limitation be pointed out with particularity in the next Action so support may be cited in response.

*35 U.S.C. 112 – Enablement*

Claims 1, 5-17 and 19-22 were rejected under Section 112, first paragraph, because it was alleged that the specification "while being enabling for the *Arabidopsis* AtNCED3 DNA comprising the nucleotide sequence of SEQ ID NO:5 encoding an amino acid sequence of SEQ ID NO:6, and a method for increasing or decreasing drought stress tolerance in *Arabidopsis* by transforming *Arabidopsis* plants with the *Arabidopsis* AtNCED3 DNA comprising the nucleotide sequence of SEQ ID NO:5 encoding an amino acid sequence of SEQ ID NO:6, does not reasonably provide enablement for other DNA molecules, or for methods of increasing or decreasing other types of stress tolerance in other species of plants." Applicants traverse for the reasons stated in the Rule 116 Amendment filed September 23, 2003 and the following.

Review of the final Office Action and the subsequent Advisory Action suggests that the following issues remain:

- (i) isolated DNA molecules encoding the protein of SEQ ID NO: 6 having up to ten amino acid substitutions are allegedly not enabled (see claims 1, 7, and 19);
- (ii) a plant simultaneously having both increased and decreased levels of expression of a neoxanthin cleavage enzyme is allegedly not enabled (see claim 8);
- (iii) a plant simultaneously having both increased and decreased amounts of ABA is allegedly not enabled (see claim 9);
- (iv) a plant having both increased and decreased levels of tolerance to any unspecified stress is allegedly not enabled (see claim 10); and

(v) methods for increasing the tolerance of a plant to any unspecified stress are allegedly not enabled (see claims 14 et seq.).

(i) In order to expedite prosecution, Applicants have canceled part (c) of claims 1, 7 and 19. Because any polypeptide that has "up to ten conservative amino acid substitutions" necessarily meets the limitations of part (d) ("at least 95% identical"), this claim amendment is not believed to restrict the scope of the amended claims. This is being done to advance prosecution in this matter. Applicants still believe that this rejection was made in error and, therefore, our arguments are made of record.

(a) Applicants' specification indeed provides guidance as to how to make and use the claimed variants. The Examiner's attention is directed to page 12, lines 8-23, wherein Applicants describe exemplary modifications. Exact points of mutation may readily be determined through routine experimentation. The test for undue experimentation is not merely quantitative since a considerable amount of experimentation is permissible, if it is merely routine, or if the specification provides a reasonable amount of guidance with respect to the direction in which the experimentation should proceed. See *In re Wands* 8 USPQ2d 1400, 1404 (Fed. Cir. 1988).

(b) The enablement decision tree, set forth in the "Training Materials For Examining Patent Applications With Respect to 35 U.S.C. §112, First Paragraph - Enablement Chemical/Biotechnical Applications," states that when the enabled embodiments (i.e., the working examples) are representative of the full scope of the claim, then the full scope of the claim is deemed to be enabled. When a claimed genus of variants is specifically limited in terms of structure and function so as to yield structurally similar polypeptides (i.e., not contain substantial variation), a single disclosed species is sufficient to represent the full scope of the genus. For example, the PTO has gone on record establishing that a genus of polypeptides having 95% sequence homology to a reference polypeptide and a specified function identical to said reference polypeptide is not substantially variable, such that a single species is sufficiently representative thereof. See Training Materials, Example 14, pages 53-55. Following this logic, the instantly claimed genus of neoxanthin cleavage enzymes, defined as having at least

589 of 599 amino acids in common (i.e., at least 98.3% homologous) would likewise lack substantial variability, such that a single working example should be deemed sufficient to represent and enable the entire genus. Thus, the Examiner's position appears to be in conflict with established PTO guidelines.

(ii)- (iv) Claims 8-10 have been amended to refer only to an "increase" which renders this portion of the rejection moot.

(v) The Examiner asserts that the instant invention is limited to the management of drought stress, yet the previous claims encompassed tolerance of any type of stress. Although Applicants clearly demonstrated that a neoxanthin cleavage enzyme gene is induced by stresses other than drought (e.g., drought, high salt concentration, and low temperature; see Example 11, page 37, lines 4-14), the Examiner summarily concluded that "a correlation between stress conditions and the induction of gene expression does not always indicate that the product of the induced gene is involved in affecting stress tolerance." Here, it does not appear that the issue raised by the Examiner concerns enablement, particularly since Applicants' specification clearly sets forth in detail how to make isolated DNA, vectors, and transformed plants according to the claims (see, for example, page 23, line 10, to page 24, line 15) as well as exemplary methods for assaying stress other than drought (see Examples 4 and 11). Rather, it appears that the Examiner is challenging the operability of the invention, more particularly the credibility of Applicants' asserted utility. Such grounds for rejection are incorrect.

As a specification is presumed to be in compliance with the enablement requirement of §112, first paragraph, so is any allegation of utility presumed to be credible unless there is reason to question the objective truth of the statement. Where Applicants have specifically asserted that an invention has particular utility, that assertion cannot simply be dismissed as wrong by the Patent Office even when there is still room for intellectual debate as to whether the asserted utility is correct. Rather, the Examiner must determine if the asserted utility is credible. An assertion is deemed to credible unless (a) the logic underlying the assertion is seriously flawed or (b) the facts upon which the assertion is based are inconsistent with the logic presented. The Examiner

must do more than merely question operability; rather, she is required to set forth facts and/or technical reasons that would lead one skilled in the art to question the objective truth of the statement of operability. The burden is firmly on the Examiner to establish that a person skilled in the art is more likely than not to doubt or question the truth of the statement of utility. In that vein, the Examiner must provide evidence (e.g., contradictory facts and/or reasoning) sufficient to establish that the skilled person would not believe Applicants' asserted utility. See M.P.E.P. § 2107.02 and *In re Brana*, 34 USPQ2d 1436 (Fed Cir. 1995).

Here, the Examiner's summary dismissal of Applicants' asserted utility does not rise to the level of "evidence" needed to overcome the presumption of operability. The fact that all genes induced by stress conditions do not affect stress tolerance does not negate Applicants' assertion that expression of the neoxanthin cleavage enzymes of the instant invention **do** increase tolerance to multiple environmental stresses, particularly drought, salinity, and cold. Whereas the Examiner's assertion is supported by nothing more than mere speculation, Applicants' assertion is supported not only by the facts and teachings of their specification but also by the prior art of Kasuga and Liu. In a fashion similar to Applicants, Kasuga and Liu discovered a factor whose expression is induced under stress conditions and that, in turn, when expressed in transgenic plants, led to marked stress tolerance. Accordingly, the findings of Kasuga and Liu support the logic of Applicants' specification and the utility asserted therein.

Thus, as the Examiner has failed to meet his burden, Applicants submit that this portion of the rejection is in error and is respectfully traversed. As an aside, Applicants note that claim 20 is limited to "drought stress" and, therefore, should not have been included in the instant rejection. Withdrawal of the enablement rejection made under Section 112, first paragraph, is requested because it would not require undue experimentation for a person of skill in the art to make and use the claimed invention.

*35 U.S.C. 112 – Definiteness*

Claims 1, 5-13 and 15-19 were rejected under Section 112, second paragraph, as being allegedly "indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention." Applicants traverse because the Examiner stated in her Advisory Action mailed December 3, 2003 that entry of the Rule 116 Amendment of September 23, 2003 overcomes the instant rejection.

Applicants request withdrawal of the Section 112, second paragraph, rejection because the pending claims are clear and definite.

*Conclusion*

Having fully responded to all of the pending objections and rejections contained in the final Office Action (Paper No. 21) and the Advisory Action (Paper No. 1103), Applicants submit that the claims are in condition for allowance and earnestly solicit an early Notice to that effect. The Examiner is invited to contact the undersigned if any further information is required.

Respectfully submitted,

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